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MLN Matters Number: MM3831

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Related CR Transmittal #: 40 and 590

Effective Date: April 4, 2005

Implementation Date: July 5, 2005

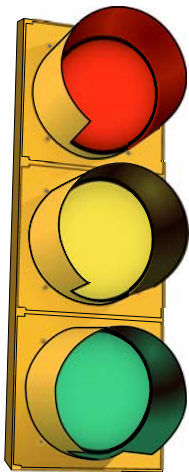
## *Coverage of Aprepitant for Chemotherapy-Induced Emesis*

**Note:** This article was revised to contain Web addresses that conform to the new CMS web site and to show they are now MLN Matters articles. All other information remains the same.

### Provider Types Affected

Providers and suppliers rendering services to beneficiaries with cancer chemotherapy-induced nausea and vomiting (CINV)

### Provider Action Needed



#### **STOP – Impact to You**

Effective April 4, 2005, you may submit claims for the use of the oral anti-emetic drug Aprepitant (Emend®), when used in combination with a 5-HT<sub>3</sub> antagonist and dexamethasone in beneficiaries receiving certain cancer chemotherapeutic agents as outlined below.

#### **CAUTION – What You Need to Know**

CMS has announced a National Coverage Determination (NCD) that covers the use of Aprepitant (Emend®), an orally administered neurokinin-1 (NK<sub>1</sub>) antagonist, in both acute and delayed phases of chemotherapy-induced emesis. Effective April 4, 2005, CMS will cover the use of the oral anti-emetic drug combination of Aprepitant (Emend®), a 5-HT<sub>3</sub> antagonist, and dexamethasone in beneficiaries receiving certain cancer chemotherapeutic agents (see *Background* section below).

#### **GO – What You Need to Do**

Make sure that your billing staffs are aware of this new coverage.

### Background

Aprepitant (Emend®), a human substance P/neurokinin-1 (NK<sub>1</sub>) receptor antagonist, is the first Food and Drug Administration-approved anti-emetic drug of its type. It has been approved to function in combination with other oral anti-emetics for the prevention of both acute and delayed chemotherapy-induced nausea

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and vomiting (CINV) associated with initial and repeat courses of highly emetogenic chemotherapeutic agents.

CINV can range in severity from mild to severe, with the most severe cases resulting in dehydration, malnutrition, metabolic imbalances, and potentially requiring withdrawal from future chemotherapy treatments. CINV incidence and severity are influenced by the specific chemotherapeutic agent(s) used, their dosage, schedule and route of administration, and by drug combinations. In addition, they can also be affected by patient-specific risk factors such as sex, age, history of motion sickness, and prior exposure to chemotherapeutic agents.

While progress has been made in reducing CINV, symptoms that occur more than a day after chemotherapy, during repeat cycles of chemotherapy, and when chemotherapy is given on more than one day or in very high doses remain hard to control. No single anti-emetic agent is completely effective in all patients.

CMS has determined that the evidence is adequate to conclude that use of the oral anti-emetic drug combination of Aprepitant (Emend®), a 5-HT<sub>3</sub> antagonist, and dexamethasone is reasonable and necessary for a specified patient population receiving one or more of the following anti-cancer chemotherapeutic agents:

- Carmustine
- Cisplatin
- Cyclophosphamide
- Dacarbazine
- Mechlorethamine
- Streptozocin
- Doxorubicin
- Epirubicin
- Lomustine

**Note:** The evidence is adequate to conclude that aprepitant cannot function alone as a full replacement for intravenously administered anti-emetic agents for patients who are receiving highly emetogenic chemotherapy.

### *Important Billing Information*

You must bill your claims for Aprepitant (Emend®), on Form CMS-1450 (UB-92), or the electronic equivalent, with the appropriate cancer diagnosis and HCPCS code of J8501 (Aprepitant, oral, 5mg) or appropriate CPT code. Those providers submitting claims to Medicare fiscal intermediaries (FIs) should also include Revenue Code 0636 (Drugs requiring detailed coding).

For FIs, the following payment methodologies apply when Aprepitant is provided by a hospitals or skilled nursing facility (SNF) outpatient department:

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- Based on Ambulatory Payment Classification (APC) for hospitals subject to the outpatient prospective payment system (OPPS);
- Under current payment methodologies for hospitals not subject to OPPS; or
- On a reasonable cost basis for SNFs.

Critical access hospital (CAH) claims will be paid as follows:

- Method I – technical services are paid at 101% of reasonable cost;
- Method II – technical services are paid at 101% of reasonable cost, and professional services are paid at 115% of the Medicare Physician Fee Schedule Data Base.

Claims submitted to Medicare's durable medical equipment regional carriers (DMERCs) will be paid based on the Average Sales Price (ASP) pricing file for claims with dates of service on or after April 4, 2005. Effective January 1, 2005, the payment allowance limit is based on the ASP + 6%.

**Note:** Inpatient claims submitted for oral anti-emetic drugs are processed under the current payment methodologies.

Your Medicare DMERC or FI will adjust claims with dates of service 04/04/05 (effective date) through 07/04/05 (implementation date), if brought to their attention.

### Additional Information

You can find more information about the coverage of Aprepitant (Emend®) for chemotherapy-induced emesis by going to <http://www.cms.hhs.gov/Transmittals/downloads/R590CP.pdf> and <http://www.cms.hhs.gov/Transmittals/downloads/R40NCD.pdf> on the CMS web site.

The file with transmittal number 40 will contain the National Coverage Determination and the file with transmittal number 590 will contain the claims processing instructions.

Finally, if you have any questions, please contact your DMERC/FI at their toll-free number, which may be found at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.pdf> on the CMS web site..

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